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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/101,672 | 10/23/1998 | ROBERT BARTLETT | 02481.1603 | 9927 |

7590 04/17/2002

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EXAMINER

WHITE, EVERETT NMN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1623

DATE MAILED: 04/17/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/101,672

Applicant(s)

BARTLETT ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 20-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17, 20-26 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2002 has been entered.
2. Applicants reply accompanying request for continued examination filed March 12, 2002 has been entered into the record.
3. Claims 12-17, 20-26 and 29 are pending in the case.
4. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

Claim Rejections - 35 USC § 103

5. Claims 12-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al (US Patent No. 4,965,276) for the reasons already of record on page 2 of the Office action mailed December 6, 1999.
6. Applicant's arguments filed March 12, 2002 have been fully considered but they are not persuasive. Applicants argue against this rejection on the grounds that the Bartlett et al patent does not disclose the full range of concentrations recited for compounds 1 and 2 of the instant claims. However, this argument is not persuasive because no more than routine skill is involved in adjusting the amount of a component of a process to suit a particular starting material in order to achieve the result taught in the prior art. Even-though the Bartlett et al patent does not disclose examples of the effectiveness of compounds 1 and 2 as part of a single pharmaceutical composition, it appears that the disclosure of the Bartlett et al patent embraces a pharmaceutical composition that comprises both compounds 1 and 2 as components of a single

composition. It is within the skill of an artisan to vary the proportion of the components of a composition to achieve the optimum effectiveness of the composition. Accordingly, the rejection of Claims 12-17 under 35 U.S.C. 103(a) as being unpatentable over the Bartlett et al patent is maintained.

7. Claims 20-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al (US Patent No. 4,965,276) for the reasons already of record on page 2 of the Office action mailed December 6, 1999.

8. Applicant's arguments filed March 12, 2002 have been fully considered but they are not persuasive. Applicant's argument with regard to the method of treating an immunological disease is not persuasive since the Bartlett et al patent discloses treatment of identical or closely similar diseases that are set forth in the instant claims (see autoimmune disease and systemic lupus erythematosus in the abstract of the Bartlett et al patent which are also set forth in the instant claims). Applicants argue that no combination of compounds 1 and 2 were tested in the Bartlett et al patent. This argument is not persuasive since the Bartlett et al patent does appear to suggest that compounds 1 and 2 may be combined in their statement disclosed at column 6, lines 28-31, which states that "the pharmaceutical products are preferably prepared and administered in dosage units, each unit containing as active ingredient a defined dose of compound 1 and/or 2." Accordingly, the rejection of Claims 20-26 under 35 U.S.C. 103(a) as being unpatentable over the Bartlett et al patent is maintained.

9. Claim 29 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al (US Patent No. 4,965,276) for the reasons already of record on page 2 of the Office action mailed December 6, 1999.

10. Applicant's arguments filed March 12, 2002 have been fully considered but they are not persuasive. The argument presented by Applicants with regard to the instantly claimed process for the preparation of a pharmaceutical composition of Claim 12 is not persuasive since changes in the concentrations of an old process do not impart patentability unless the recited ranges are critical, i.e., they produce a new and

unexpected result. No new and unexpected result has been disclosed. Accordingly, the rejection of Claim 29 under 35 U.S.C. 103(a) as being unpatentable over the Bartlett et al patent is maintained.

11. **Summary:** All the pending claims of record are rejected.

Action Made Final

12. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

13. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-

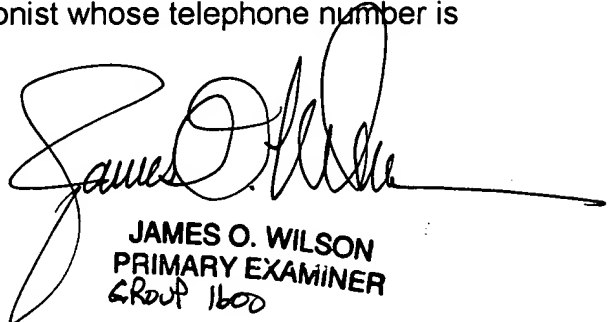
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4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reach on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
E.White


JAMES O. WILSON
PRIMARY EXAMINER
Group 1600